



PATENT
ATTORNEY DOCKET NO.: 044574-5040-US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
)
Patrick C. KUNG *et al.*)
)
Application No.: 09/830,033) Group Art Unit: 1631
)
Filed: October 22, 2001) Examiner: Cheyne D. Ly
)
For: PHYTOMICS: A GENOMIC-BASED APPROACH TO)
HERBAL COMPOSITIONS)

Commissioner for Patents
Washington, D.C. 20231

Sir:

DECLARATION UNDER 37 C.F. §1.132

I, Dan Theodorescu, M.D., Ph.D., declare as follows:

1. I am presently Director of the Paul Mellon Prostate Cancer Institute, Professor of the Department of Molecular Physiology and Biological Physics, Professor of the Department of Urology, the Paul Mellon Chair in Urologic Oncology, an Attending Urologist at University Hospital, and Urologic Oncologist at the Cancer Center, all located at the University of Virginia, Charlottesville, Virginia. A copy of my curriculum vitae is attached as Exhibit A.
2. I have read and am familiar with International Patent Application No. WO 00/24934, entitled *Phytomics: A Genomic-Based Approach to Herbal Compositions*, with inventors Patrick C. KUNG and Young Chi CHENG, and applicant Yale University ("the Yale patent application"), originally filed on October 23, 1998. I have been informed that the Yale patent application is

licensed exclusively to PhytoCeutica Inc., a company headquartered in New Haven, Connecticut. The Yale patent application discloses and claims a method of evaluating the biological equivalency for the purpose of quality control of an herbal composition, wherein the method includes comparing the genomic expression pattern (*i.e.*, test bioresponse array) generated by exposing a biosystem to the herbal composition to a genomic expression pattern (*i.e.*, standardized herbal bioresponse array) collected from the same or substantially the same herbal composition that is considered the botanical standard.

3. I have reviewed and understand the claims 83 – 87 that are presently pending in the Yale patent application.
4. I have read and understand the Final Office Action that was mailed by the U.S. Patent and Trademark Office on February 24, 2004 regarding the Yale patent application, particularly paragraphs 16 – 27 on pages 5-7 (*i.e.*, the claim rejections under 35 U.S.C. § 103). It is my understanding that the Patent Examiner maintains that claims 83 – 87 are not patentable in view of the teachings of Khwaja *et al.* (U.S. Patent No. 6,113,907) in view of Schena *et al.* (Parallel human genome analysis: Microarray-based expression monitoring of 1000 genes. *Proc. Natl. Acad. Sci USA* 93:10614-10619. 1996). I have read and understand Khwaja *et al.* and Schena *et al.*
5. Complementary and alternative therapies offer opportunities and novel insights for the treatment and prevention of neoplastic diseases. We have recently shown that 43% of men with localized prostate cancer (CaP) use herbal complementary therapies (Lippert, M. C., McClain, R., Boyd, J. C., and Theodorescu, D. Alternative medicine use in patients with localized prostate carcinoma treated with curative intent. *Cancer*, 86: 2642-2648, 1999). These prevalence rates varied

as a function of age and aggressivity of the cancer. In addition, we have shown that many patients are highly motivated to use these therapies due to their relatively low toxicity profile (Hall, J. D., Bissonette, E. A., Boyd, J. C., and Theodorescu, D. Motivations and influences on the use of complementary medicine in patients with localized prostate cancer treated with curative intent: results of a pilot study. *BJU Int*, 91: 603-607, 2003). However, most compelling was the finding that several of these botanical therapies show striking and beneficial clinical effects on human CaP as well as in experimental in vitro studies. One such example is PC-SPES, a combination of 8 herbal extracts that has significant clinical benefits for patients with metastatic, hormone-refractory CaP.

Dr. Eric Small, an oncologist at University of California San Francisco reported in 2000 that BotanicLab's PC-SPES lowered PSA and shrank tumors in men with advanced prostate cancer. Furthermore, in 2002 Dr. Small and Dr. William Oh at Dana Farber opened a randomized trial to compare PC-SPES with Diethylstilbestrol (DES), an artificial estrogen in view of the fact that PC-SPES is known to have estrogenic effects. All of the patients had androgen independent prostate cancer; none of them had received chemotherapy or other advanced therapy. As this trial began to accrue, men who received PC-SPES actually did better than men receiving DES (although not quite as well as patients taking PC SPES in the earlier study). Patients enrolled in the PC SPES arm of the trial were showing better responses than those receiving DES. Of the PC SPES group, 45% had at least a 50% drop in PSA (prostate specific antigen, a biochemical marker of prostate cancer). Only 21% of those on DES experienced a 50% drop.

Unfortunately, and pertinent to this application, in late 2002, the aforementioned trial was stopped prematurely by the FDA because of ongoing concerns about the contents of PC-SPES. A few months before this, lots of PC-SPES tested had

small amounts of DES and other pharmaceuticals present. Although, in view of the trial design, the DES contamination of the PC-SPES would not have been a source of the improved effects of PC-SPES in patients (since the trial compared it to pure DES), nevertheless study of this very promising herbal medication was halted. This problem was further compounded by a clinical observation made by most oncologists, namely that the side effects of PC-SPES in patients seemed to depend not only on patient profiles but also on the lots of PC-SPES they were taking. Hence, this suggested that the lot to lot variability of the product was significant and that the company at that time (circa 2000-2002) despite 1) the prior publication of Khwaja *et al* and Schena *et al*; and 2) their in house quality control processes, did not have the idea or vision to formulate a quality control process based on gene expression profile which could have prevented these problems.

It is particularly important to place in perspective why nobody until our group in 2003 (Bigler, D., Gulding, K. M., Dann, R., Sheabar, F. Z., Conaway, M. R., and Theodorescu, D. Gene profiling and promoter reporter assays: novel tools for comparing the biological effects of botanical extracts on human prostate cancer cells and understanding their mechanisms of action. *Oncogene*, 22: 1261-1272, 2003, copy attached as Exhibit B) demonstrated this approach toward quality control of herbal products and consequently why, the current patent application by Patrick C. KUNG *et al*. has great merit. Consider these facts: 1) The two papers quoted above (Khwaja *et al* and Schena *et al*) are in very disparate areas of science. It is not customary for someone working in botanical products to be familiar with and/or scan the gene expression molecular biology literature routinely. Science today is highly complex and specialized and significant developments on none area (as would have been the case with cDNA microarrays in 1995) were not "common knowledge" even in molecular biology circles, let alone, in individuals working in botanical products. 2) The mindset and approach of workers in the botanical field for many years and certainly in the early nineties

was very descriptive and non scientific, with scientific research (basic science) and/or clinical trials of these products being rare. 3) Our laboratory, in 2002 began work which culminated in the formulation of an approach using gene expression profiling for quality control of botanical products (Bigler reference above). It is important to understand that my laboratory and my research program is one which is fundamentally carrying out translational research and therefore is grounded in both molecular biology and clinical medicine. Thus, it was this unique combination that allowed us to formulate and synthesize the approach to combine gene expression profiling to a clinically relevant problem, made so by the unfortunate collapse of the PC-SPES trial; a trial that is completed may have produced a novel and effective therapeutic strategy for metastatic prostate cancer. In addition, it is not at all obvious that even in my lab we would have thought of this concept in 1998, the time this patent was filed. 4) Finally, despite the prior publication of Khwaja *et al* and Schena *et al* and their in house quality control processes, BotanicLab, the makers of PC-SPES, did not have the idea or vision to formulate a quality control process based on gene expression profile which could have prevented the lot to lot variability that plagued their product in 2000-2002. 5) Khwaja *et al.* disclose using compositional and bioactivity fingerprints for the processing of St. John's Wort to produce botanical drugs. Their disclosed method includes measuring selective muscarinic M1 receptor binding inhibition of samples of St. John's Wort. The methods taught by Khwaja *et al.* do not include using gene expression profiles for quality control. Schena *et al.* disclose using microarray-based expression monitoring of genes to identify known and novel heat shock and phorbol ester-regulated genes in human T cells. Schena *et al.* involves the identification of heat shock and phorbol-ester-regulated genes using microarray-based expression. They do not provide any guidance on how one would utilize a differential gene expression profile of multiple genetic components in a quality control method for assessing the equivalency of herbal compositions.

In summary, for the above 5 reasons I believe that it was NOT obvious to an artisan of ordinary skill to combine the works of Khwaja *et al* and Schena *et al* and formulate a proposal similar to the proposed patent by Patrick C. KUNG *et al.* in 1998.

6. As support for my position as stated in paragraph 2 above, I attach as Exhibit B a copy of an article entitled *Gene profiling and promoter reporter assays: Novel tools for comparing the biological effects of botanical extracts on human prostate cancer cells and understanding their mechanisms of action*, (Bigler *et al.*, Oncogene 22:1261-1272 (2003)). I am a co-author of this article reporting on the results of using PC-SPES, a combination of eight herbs, “as a model system to demonstrate ‘proof of principle’ as to how gene expression profiling coupled with promoter assays can evaluate the effect of herbal cocktails on human prostate cancer” (Abstract). We realized that during these studies, and stimulated by the Quality Control (“QC”) debacle of PC-SPES in 2002 as described above, that the expression profile could in fact be a very powerful biological metric for botanical QC. Hence, we hypothesized the following:

“This finding has profound implications since it potentially offers an avenue for the molecular ‘fingerprinting’ of complex botanical extracts, which are claimed to be made from the same natural sources. Application of these approaches in preclinical studies may allow for both the standardization of the botanical mixtures allowing for rational interpretation of any discrepant human clinical data. In addition, companies producing botanical products can use this technology in quality assurance of their products, which may have biological relevance superior to conventional approaches such as HPLC.” Page 1266, second column.

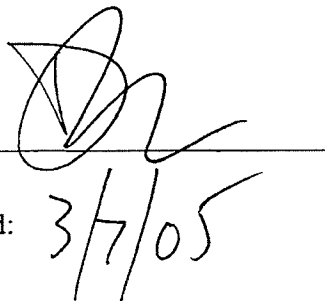
Importantly, even in this 2003 publication the original purpose of the study was to assess and compare mechanisms of action between two different botanical formulations and that the observation of the utility of using gene expression

profiles for quality control of botanicals was actually an afterthought. Thus, as mentioned above in paragraph 5, it is my belief that one of ordinary skill in the herbal medicine arts could not have arrived at the invention now claimed in the Yale application in 1998 based on the combined teachings of Khwaja *et al.* and Schena *et al.* It is also my belief that the invention now claimed in the Yale patent application could have real utility for determining an advanced form of quality control for botanical extracts and provides an important advancement in the standardization of herbal compositions.

7. I further declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true, and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

By: _____

Dated: _____

A handwritten signature, appearing to be 'DZ', is written over a horizontal line. Below the signature, the date '3/7/05' is handwritten.

CURRICULUM VITAE

Dan Theodorescu MD PhD



PERSONAL

LANGUAGES SPOKEN: *English, French, Romanian*
MARITAL STATUS: *Married to Diane Louise Causier*
CHILDREN: *Thomas William (DOB 1/26/95)*
Claire Ana (DOB 10/6/96)

CURRENT ADDRESS

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ACADEMIC DEGREES

1993 *Doctor of Philosophy (PhD)*
University of Toronto, Toronto, Ontario, Canada.
1986 *Doctor of Medicine (MD)*
Queen's University, Kingston, Ontario, Canada.

POSITIONS HELD

University of Virginia, Charlottesville, VA

2003-present *Director, Paul Mellon Prostate Cancer Institute*
2002-present *Professor, Department of Molecular Physiology and Biological Physics*
2001-present *Professor, Department of Urology*
1998-present *Paul Mellon Chair in Urologic Oncology, Department of Urology*
1995-present *Attending Urologist, University Hospital*
1995-present *Urologic Oncologist, Cancer Center*

2001-2002 *Associate Professor, Department of Molecular Physiology and Biological Physics*
1998-2001 *Associate Professor, Department of Urology*
1995-2001 *Assistant Professor, Department of Molecular Physiology and Biological Physics*
1995-1998 *Assistant Professor, Department of Urology*

PROFESSIONAL CERTIFICATIONS

1999 Certified by the American Board of Urology
1998 Fellow of the American College of Surgeons (*FACS*)
1995 Medical License in the State of Virginia
1995 Fellow of the Royal College of Physicians and Surgeons of Canada (*FRCSC*)
1994 Certified by the Royal College of Physicians and Surgeons of Canada in Urology
1986 Licentiate of the Medical Council of Canada (*LMCC*)

ADMINISTRATION AND COMMITTEES

1995-1999	Tumor Registry Committee, University of Virginia, Charlottesville, VA
1996-1997	AFUD Bladder Health Council, USA: <i>Bladder cancer awareness week organizing committee</i>
1996-1999	ECOG Genitourinary Committee, USA
1997-1999	American Cancer Society, Prostate Cancer Planning Committee, Virginia Chapter
1999-2003	Basic Cardiovascular Research Training Grant Executive Committee, University of Virginia, Charlottesville, VA
2000	Member, Dean's Search Committee for Chairman, Department of Pathology
2001-2003	Member, Executive Management Committee, Tyco/US Surgical Laparoscopic Center of Excellence, University of Virginia, Charlottesville, VA
2001-2003	Member, Internal Advisory Board, Paul Mellon Prostate Cancer Institute, University of Virginia, Charlottesville, VA
2001-present	Member, Cancer Center Seminar Series Committee, University of Virginia, Charlottesville, VA
2003-present	Member, American Urological Association (AUA) Research Council.
2003-present	Director, Paul Mellon Prostate Cancer Institute
2004-2007	Nominations Committee for the Society for Basic Urology Research (SBUR)

MEMBERSHIPS IN PROFESSIONAL ASSOCIATIONS

2001-present	European Association of Urology (EAU)
1998-present	American College of Surgeons (ACS)
1998-present	Society for Urologic Oncology (SUO)
1998-present	American Urological Association (AUA)
1995-present	Medical Society of Virginia
1995-present	Eastern Cooperative Oncology Group (ECOG)
1995-present	American Society for Clinical Oncology (ASCO)
1989-present	American Association for Cancer Research (AACR)
1989-present	Society for Basic Urologic Research (SBUR)
1995-1998	American College of Surgeons (ACS)(<i>Associate Member</i>)
1993-1998	American Urological Association (AUA)(<i>Candidate Member</i>)

JOURNAL EDITORIAL BOARDS

2004-present	<i>British Journal of Urology-Investigative Section</i>
2004-present	<i>Current Cancer Therapy Reviews</i>
2003	<i>Guest editor: Urologic Clinics of North America: "Followup of GU cancers"</i>
2003-present	<i>BMC Medicine</i>
2003-present	<i>Cancer Letters</i>
2002-present	<i>World Journal of Urology (Research section editor)</i>
2002-present	<i>BMC Cancer</i>
2002-present	<i>BMC Urology</i>
2000-present	<i>Journal of Laparoendoscopic and Advanced Surgical Techniques</i>
2000-present	<i>E-Medicine Textbook of Urology (www.emedicine.com)</i>
2000-present	<i>Prostate Cancer and Prostatic Diseases</i>

JOURNAL REVIEWER

2003-present	<i>British Journal of Urology</i>
2003-present	<i>Cancer Cell</i>
2002-present	<i>Molecular and Cellular Biology</i>

2002-present	<i>Journal of the National Cancer Institute</i>
2001-present	<i>Cancer Practice</i>
2000-present	<i>Proceedings of National Academy of Science (USA)</i>
2000-present	<i>Nutrition and Cancer</i>
2000-present	<i>Clinical Cancer Research</i>
2000-present	<i>International Journal of Cancer</i>
1998-present	<i>Urologic Oncology</i>
1998-present	<i>Cancer Research</i>
1998-present	<i>Journal of Laparoendoscopic and Advanced Surgical Techniques</i>
1998-present	<i>Urology</i>
1997-present	<i>British Journal of Cancer</i>
1996-present	<i>American Journal of Pathology</i>
1996-present	<i>Clinical Chemistry</i>
1996-present	<i>Cancer</i>
1994-present	<i>Journal of Urology</i>

EDUCATIONAL HISTORY

1994-1995	<i>Clinical Fellow</i> , Urology Service, Memorial Sloan-Kettering Cancer Center, New York, NY.
1991-1994	<i>Resident</i> , Division of Urology, Department of Surgery, University of Toronto, Toronto, Ont.
1988-1991	<i>MRC Research Fellow</i> , Mount Sinai Hospital Research Institute, Faculty of Medicine, University of Toronto, Toronto, Ont.
1986-1987	<i>Surgical Internship</i> , Department of Surgery, University of Toronto, Toronto, Ont.
1982-1986	<i>Medical School</i> , Faculty of Medicine, Queen's University, Kingston, Ont.
1980-1982	<i>Undergraduate Studies</i> , Department of Chemistry, Queen's University, Kingston, Ont.

HONORS AND AWARDS

2004	<i>American Urological Association (AUA) Leadership Program</i>
2002	<i>American Association for Cancer Research (AACR) Sydney Kimmel Award</i>
1999	<i>Resident Teaching Award</i> , Department of Urology, University of Virginia
1998	<i>Paul R. Mellon Chair in Urologic Oncology</i> , Department of Urology, University of Virginia.
1998	<i>Young Investigator Award from the Society for Basic Urologic Research</i>
1998	<i>Edwin Beer Award from the New York Academy of Medicine</i>
1997	<i>Kimmel Foundation Scholar</i>
1996	<i>Recipient of American Cancer Society Career Development Award</i>
1996	<i>Recipient of American College of Surgeons Faculty Research Fellowship</i>
1992	<i>American Urologic Association (N-E and New England Sections) Resident Essay Third Prize</i>
1992	<i>Bard Canada Resident Essay Prize</i> , Division of Urology, University of Toronto.
1991	<i>J.C. Laidlaw Prize</i> (First Place) for Research Excellence, Faculty of Medicine, University of Toronto.
1991	<i>Gallie Bateman Prize</i> (First Place) in Surgical Research, Dept. of Surgery, University of Toronto.
1990	<i>Davis and Geck Resident Essay Prize</i> , Division of Urology, University of Toronto.
1990	<i>Gallie Bateman Prize</i> (Second Place) in Surgical Research, Dept. of Surgery, University of Toronto.
1990	<i>Fellow of the Medical Research Council of Canada.</i>
1990	<i>Canadian Urologic Association Resident Essay Prize</i>
1989	<i>J.C. Laidlaw Prize</i> (Honorable Mention) for Research Excellence, University of Toronto.
1986	<i>Zbar Prize</i> , Faculty of Medicine, Queen's University.
1985	<i>Senator Frank Carell Award</i> for Academic Achievement Faculty of Medicine, Queen's University
1983	<i>Leukemia Research Prize</i> , for Research Excellence from the Canadian Leukemia Research Fund.
1982	<i>Dean's List in the Faculty of Arts and Science</i> , Queen's University.

NATIONAL AND INTERNATIONAL LECTURES AND PANELS

- 2005 **2005 International Bladder Symposium**, Baltimore, MD
 Title: "RhoGDI2, a new metastasis suppressor gene in bladder cancer: Discovery and clinical translation"
- 2004 **Global GU Oncology Conference**, Honolulu, HI
 Title: "How shall we manage locally advanced prostate cancer? Matched comparison of Brachytherapy and Radical prostatectomy"
- 2004 **Plenary Session Moderator: Controversies in Penile Cancer**
 Global GU Oncology Conference, Honolulu, HI.
- 2004 **83rd Annual Meeting of the Clinical Society of Genitourinary Surgeons**, Charlottesville, VA
 Title: "RhoGDI2, a new metastasis suppressor gene in bladder cancer: Discovery and clinical translation"
- 2004 **Baylor University: Department of Urology**, Dallas, TX.
 Title: "Clinical follow up in urologic oncology"
- 2004 **Marshfield Clinic: Oncology Center**, Marshfield WI.
 Title: "The role of RhoGDI2 in human bladder cancer"
- 2003 **5th Society for Urologic Oncology (SUO)**
 Title: "RhoGDI2: the role and mechanism of action of a new metastasis suppressor gene"
- 2003 **8th Annual Scottsdale Prostate Cancer Conference**, Scottsdale, AZ.
 Title: "Molecular Staging of Genitourinary Cancers"
- 2002 **Society for Basic Urologic Research Conference**, Orlando, FL.
 Title: "Angiogenesis: VEGF in prostate cancer"
- 2002 **American Association for Cancer Research (AACR)**, San Francisco, CA.
 Title: "Mechanisms of PTEN mediated cell motility: Role of protein phosphatase activity"
- 2002 **Medical College of Virginia 2nd Annual Warren Koontz Urology Conference**, Richmond, VA.
 Title: "Current Status of Cryotherapy for Genitourinary Cancers"
- 2002 **Virginia Urology Center 3rd Annual Urology Conference**, Richmond, VA.
 Title: "Current Status of Continent Diversions following cystectomy for Bladder Cancer"
- 2001 **NIH-Bladder Cancer PRG, Panel Member**, Washington, DC.
 Panel: Panel make consensus recommendations for the NIH priorities in bladder cancer research
- 2001 **American Brachytherapy Society Consensus Panel Member**, Nassau, Bahamas.
 Title: "Current Status of Hormonal therapy in localized Prostate Cancer treated with brachytherapy"
 Panel: Panel includes 10 members which make consensus recommendations for the ABS
- 2001 **Virginia American Cancer Society**, Fredericksburg, VA.
 Title: "Current Status of Alternative medicine Use in Prostate Cancer"
- 2001 **Medical College of Virginia 1st Annual Warren Koontz Urology Conference**, Richmond, VA.
 Title: "Current Status of Tumor Markers in Bladder Cancer"
- 2001 **Prostate Cancer Update: Kimmel Cancer Center, Philadelphia**, Philadelphia, PA.
 Title: "Molecular Regulation of Angiogenesis in Prostate cancer"
- 2000 **State of the Science in Superficial Bladder Cancer: NCI Sponsored workshop**, Washington, DC.
 Title: "EGF receptor signal transduction in bladder cancer invasion"
- 2000 **International Innovators in Urology**, Dublin, Ireland.
 Title: "The role of VEGF in prostate cancer metastasis"
- 2000 **Department of Urology, Ohio State University**, Columbus, OH.
 Title: "Sexual and voiding function and quality of life in prostate cancer"
- 1999 **Urology Investigators Forum (UIF) Society**, New York, NY.
 Title: "Sexual and voiding function and quality of life in prostate cancer"
- 1999 **International Innovators in Urology**, Cambridge, England.
 Title: "Quality of life in prostate cancer: Brachytherapy vs. radical surgery"
- 1999 **Long Island Jewish Medical Center**, New York, NY
 Title: "Molecular biology of prostate cancer progression: The role of dietary fatty acids"
- 1998 **Festschrift for Dr. William Fair, Chair Urology Service Memorial Sloan Kettering, 1984-1997**
 New York, NY
 Title: "Molecular staging of prostate cancer"

- 1998 **"International Innovators in Urology"**, London, England.
Title: "Molecular staging of prostate cancer"
- 1998 **"Molecular genetics of bladder cancer: NCI Sponsored workshop"**, Sarasota, FL.
Title: "EGFR signaling in TCC progression"
- 1998 **University of Tennessee**, Knoxville, TN
Title: "Molecular biology of prostate cancer development: The role of angiogenesis"
- 1997 **American Foundation for Urological Disease**, American Urological Association, New Orleans, LA
Title: "Bladder Health Week 1996: Update and Results"
- 1997 **Eastern Cooperative Oncology Group (ECOG) GU Group**, Atlanta, GA
Title: "Using EGFR inhibitors in the prevention of high grade T1 TCC progression"
- 1997 **Moderator, Podium Session on Human Therapeutics**
Conference: American Cancer Society, Virginia Chapter, Richmond, VA.
- 1997 **Maimonides Medical Center**, Brooklyn, NY
Title: "Molecular biology in staging, prognosis and treatment of prostate cancer"
- 1996 **Eastern Cooperative Oncology Group (ECOG) GU Group**, Baltimore, MD
Title: "The role of p53, bcl-2 and Rb markers in localized prostate cancer progression"
- 1995 **Medical College of Virginia**, Richmond, VA
Title: "The role of p53 in T1 bladder cancer progression"
- 1992 **Department of Urology, M.D. Anderson Hospital and Tumor Institute**, Houston, TX.
Title: "Ha-ras and EGF-R expression in transitional cell carcinoma growth and invasion"
- 1992 **Fourth International Congress of The Metastasis Research Society**, Paris, France.
Title: "Suppression of TGF-beta1 secretion enhances the aggressiveness of colon cancer"
- 1991 **Co-Chairperson, Poster Discussion Session on Biology of Metastasis**
Conference: American Association for Cancer Research, Houston, Texas.
- 1990 **International Molecular Genetics of Bladder Cancer Meeting**, Prouts Neck, MA
Title: "Ha-ras and EGF-R expression in transitional cell carcinoma growth and invasion"

PROFESSIONAL SOCIETY PROGRAMS

- 2005 **Plenary Session Pannelist: Controversies in Superficial Bladder Cancer**
American Urological Association, San Antonio, TX.
- 2005 **Postgraduate Course in Urologic Oncology**, American Urological Association, San Antonio, TX.
Title: "Clinical follow up in urologic oncology"
Participants: Dr. S. Machele Donat (director)
- 2005 **Program Committee: Bladder Cancer**
Conference: American Urological Association, San Antonio, TX.
- 2004 **Instructor, AUA-Basic Science for Urologists Course**
Title: "Basic molecular biology for urologists"
Conference: American Urological Association (AUA) Sponsored course, Charlottesville, VA.
- 2004 **Co-Moderator, Poster Discussion Session: Bladder Cancer Research I**
Conference: American Urological Association, San Francisco, CA
- 2004 **Program Committee: Bladder Cancer**
Conference: American Urological Association, San Francisco, CA.
- 2004 **Postgraduate Course in Urologic Oncology**, American Urological Association, San Francisco, CA.
Title: "Clinical follow up in urologic oncology"
Participants: Dr. S. Machele Donat (director)
- 2004 **Co-Moderator, Metastasis Podium Session**
Conference: American Association for Cancer Research (AACR), Orlando, FL.
- 2003 **Moderator, Plenary Session: Molecular therapeutics**
Conference: Society for Urologic Oncology (SUO), Bethesda, MD.
- 2003 **Instructor, AUA-Basic Science for Urologists Course**
Title: "Basic molecular biology for urologists"
Conference: American Urological Association Sponsored course, Charlottesville, VA.

- 2003 **Co-Moderator, Poster Discussion Session: Bladder Cancer Research II**
Conference: American Urological Association, Chicago, IL.
- 2003 **Postgraduate Course in Urologic Oncology**, American Urological Association, Chicago, IL
Title: "Clinical follow up in urologic oncology"
Participants: Dr. S. Machele Donat (director)
- 2002 **Program Committee: Bladder Cancer Sessions**
Conference: American Urological Association, Chicago, IL.
- 2002 **Plenary Session Summary: Highlights of Prostate Cancer Sessions**
Conference: Soci  t   Internationale d'Urologie (SIU), Stockholm.
- 2002 **Co-Moderator, Podium Session on Prostate Cancer**
Conference: American Urological Association-Mid Atlantic Section, Baltimore, MD.
- 2002 **Instructor, AUA-Basic Science for Urologists Course**
Title: "Basic molecular biology for urologists"
Conference: American Urological Association Sponsored course, Charlottesville, VA.
- 2002 **Plenary Session Summary: Highlights of Bladder Cancer Sessions**
Conference: American Urological Association, Orlando, FL.
- 2002 **Program Committee: Abstract review team (bladder cancer)**
Conference: American Urological Association, Orlando, FL.
- 2001 **Co-Moderator, Podium Session on Advanced Bladder Cancer**
Conference: American Urological Association, Anaheim, CA.
- 2000 **Plenary Session Lecture**
Title: "Penile Cancer: Diagnosis and Staging"
Conference: Soci  t   Internationale d'Urologie (SIU), Singapore.
- 2000 **Moderator, Kidney Cancer Poster Session**
Conference: Soci  t   Internationale d'Urologie (SIU)", Singapore.
- 2000 **Chairman, Scientific Program Committee**
Conference: American Urological Association-Mid Atlantic Section, Puerto Rico.
- 1999 **Member, Scientific Program Committee**
Conference: American Urological Association-Mid Atlantic Section, Hilton Head, NC
- 1999 **Postgraduate Course in Urologic Oncology**, American Urological Association, Dallas, TX
Title: "Clinical follow up in urologic oncology"
Participants: Drs. William Fair (director), Michele Donat and Guido Dalbagni
- 1998 **Resident Essay Prize Selection Committee**
Conference: American Urological Association-Mid Atlantic Section, Palm Beach, FL.
- 1998 **Co-Moderator, Podium Session on Prostate Cancer**
Conference: American Urological Association-Mid Atlantic Section, Palm Beach, FL.
- 1998 **Virginia Urological Society Annual Meeting**, Virginia Urological Society, Charlottesville, VA
Title: "Continent diversions in women: Pearls and pitfalls"
- 1998 **Postgraduate Course in Urologic Oncology**, American Urological Association, San Diego, CA
Title: "Clinical follow up in urologic oncology"
Participants: Drs. William Fair (director), Michele Donat and Guido Dalbagni
- 1996 **Virginia Urological Society Annual Meeting**, Virginia Urological Society, Richmond, VA
Title: "The role of molecular markers in bladder cancer progression",

CME COURSES AND SYMPOSIA

- 2003 **"Richmond Urologic Forum"**, Richmond, VA.
Lecture 1 Title: "Current Status of Continent Diversions following cystectomy for Bladder Cancer"
Lecture 2 Title: "Clinical follow up in urologic oncology"
- 2001 **Third Annual Mid Atlantic Urology Seminar**, Banff, Alberta
Title: "Second opinion pathologic review in bladder cancer: Costs and benefits"
- 2000 **"Management of Prostate Cancer in the Year 2000"**, Atlanta, GA
Title: "Quality of life following treatment of localized prostate cancer"

- 2000 **"20th Annual Jackson Hole Urology Conference"**, Jackson Hole, WY
Title: "Molecular prognostic factors in prostate cancer"
- 1999 **Second Annual Mid Atlantic Urology Seminar**, Taos, NM
Title: "Molecular staging of prostate cancer"
- 1998 **Virginia Beach Cancer Center**, Virginia Beach, VA
Title: "Molecular biology in staging, prognosis and treatment of prostate cancer"
- 1998 **Department of Surgery Grand Rounds, University of Virginia**, Charlottesville, VA
Title: "The emerging role of brachytherapy in the treatment of localized prostate cancer"
- 1998 **First Annual Mid Atlantic Urology Seminar**, Montreal, Quebec
Title: "Partial nephrectomy: Emerging role in management of renal cell cancer"
- 1997 **36th Annual Medical Staff Oncology Seminar**, Halifax Regional Hospital, South Boston, VA
Title: "New advances in prostate cancer brachytherapy"
- 1997 **Day at Virginia, University of Virginia**, Charlottesville, VA
Title: "The role of lymphadenectomy in the treatment of penile cancer"
- 1997 **Prostate Brachytherapy Course, University of Virginia**, Charlottesville, VA
Title: "The use of chemosensitizers in prostate cancer radiotherapy"
Note: Two day course every two months
- 1995 **Course in Prostate Oncology, Rockingham Memorial Hospital**, Harrisonburg, VA
Title: "Prostate specific antigen (PSA): New advances"
- 1995 **Day at Virginia, University of Virginia**, Charlottesville, VA
Title: "Partial nephrectomy: Who ? Why ? and How ?"
- 1995 **Course in Surgical Oncology, University of Virginia**, Charlottesville, VA
Title: "Novel treatments of localized prostate cancer"

STRUCTURED TEACHING

- 1993 Third Year medical students (St. Michael's Hospital, University of Toronto, Toronto, Ont.)
Time: 2hrs/week x 12 weeks
Topic: General Urology
- 1995-present Department: Urology
Level: Third year medical students
Time: 1 hr/month
Topic: Bladder Cancer
- 1997-2002 Department: Molecular Physiology and Biological Physics (Physiology 852)
Course/Level: Graduate students
Time: 1.5 hr/6 months
Topic: Tumor Angiogenesis
- 1999-2002 Department: Microbiology (Molecular Basis of Cancer)
Level: Graduate students
Time: 2 hr/6 months
Topic: Tumor Angiogenesis

TRAINING GRANT FACULTY

Principal Investigator:	Sarah J. Parsons
Project Number:	5T32CA09109-24
Source:	National Cancer Institute

Last Update: Tuesday, February 08, 2005

Title of Project:	Cancer Research Training In Molecular Biology
Principal Investigator:	Brian Duling
Project Number:	5T32HL07284-23
Source:	National Heart, Lung, And Blood Institute
Title of Project:	Basic Cardiovascular Research Training Grant
Principal Investigator:	Gary Owens
Project Number:	N/A
Source:	NIH
Title of Project:	MD/PhD Training Grant
Principal Investigator:	Michael Weber
Title of Project:	Molecular Medicine program

UNDERGRADUATE AND MEDICAL STUDENTS

1997 summer	John Tiedman (summer research student)
1997-1998	Michael Emmanuel Herce (mentor for Biology 495-496 Research Project)
1998 summer	Sayeh Farivar (NIH summer undergraduate research student)
1999 summer	Anna Jackson (NIH summer undergraduate research student)
2000 summer	Chris Geiger (NIH summer undergraduate research student)
2000 summer	Lex Thomas (UVA Cancer Center medical student)
2001 summer	Joshua Hall (NIH Alternative Medicine Center medical student)

GRADUATE STUDENTS

1996-2000	Amy Ma (member of PhD thesis committee: Department of Microbiology)
1997-2002	Paul D. Deeble (member of PhD thesis committee: Department of Microbiology)
1998-2002	Robert E. Bakin (member of PhD thesis committee: Department of Microbiology)
2001-2004	Brian E. Nicholson (PhD supervisor: Department of Molecular Physiology)
2004-present	Steven Smith (PhD supervisor: Department of Molecular Physiology)
2004-present	David Chernauskas (PhD supervisor: Department of Molecular Physiology)
2004-present	Rooshin Dalal (member of PhD thesis committee: Department of Cell Biology)

RESIDENTS AND CLINICAL RESEARCH FELLOWS

1995-1996	Stanford Broder MD (urology resident doing clinical research). <i>Dr. Broder has been the recipient of the 3rd prize for clinical research at the 1997 American Urological Association meeting for his contribution to publication #25)</i>
1996-1997	Emin Ozbek MD (clinical urology research fellow)
1996-1997	Christopher Crane (radiation oncology resident doing clinical research)
1998-1999	Tracy Krupsky MD (urology resident doing basic and clinical research) <i>Dr. Krupski has been the recipient of the University of Virginia School of Medicine Resident prize for research for 2000, for her contribution to publication #43)</i>
1998-2000	Brant Fulmer MD (urology resident doing clinical research)
1999-2001	Terrance Chapman MD (urology resident doing clinical research)
2000-2003	Timothy Coblentz MD (urology resident doing clinical research) <i>Dr. Coblentz has been the recipient of the 1st prize for clinical research at the 2000 Mid-Atlantic American Urological Association meeting for his contribution to publication #51)</i>
2000-2004	Emily Smith MD (urology resident doing clinical research)

Last Update: Tuesday, February 08, 2005

2001-2005	Nicole Miller MD (urology resident doing clinical research) <i>Dr. Miller has been the recipient of the 1st prize for clinical research at the 2004 Mid-Atlantic American Urological Association meeting for her contribution to publication #51)</i>
2001-2005	Antoine Maklouf MD PhD (urology resident doing clinical research)
2002-present	Jeff Woolsey MD (urology resident doing clinical research)
2003-present	Hillary Copp MD (urology resident doing clinical research)
2003-present	Sophie Fletcher MD (urology resident doing clinical research)
2004-present	Sarah Coleman MD (urology resident doing clinical research)

POSTDOCTORAL FELLOWS

1995-1996	François LeGal PhD (postdoctoral supervisor)
1997-present	Michael Harding PhD (postdoctoral supervisor) <i>Dr. Harding is the recipient of an NIH Training Grant, 1997-2000) and the recipient of the Pfizer Scholar in Urology Award for Urological research in 1999.</i>
1998-2002	John Gildea PhD (postdoctoral supervisor) <i>Dr. Gildea is the recipient of an American Foundation of Urologic Disease AFUD fellowship, 1999-2002</i>
1998-2001	Essam Sheeta PhD (postdoctoral supervisor) <i>Dr. Sheta is the recipient of an NIH Training Grant, 1999-2001</i>
1999-2002	Jabed Seraj MD PhD (postdoctoral supervisor) <i>Dr. Seraj is the recipient of an NIH Training Grant, 2000-2001</i>
2001-present	Dora Bigler PhD (postdoctoral supervisor)
2001-present	Gary Oxford PhD (postdoctoral supervisor) <i>Dr. Oxford is the recipient of an NIH Training Grant, 2002-2005</i>
2001-present	Mikel Herlevsen PhD (postdoctoral supervisor)
2002-present	Brian Titus PhD (postdoctoral supervisor) <i>Dr. Titus is the recipient of an American Foundation of Urologic Disease AFUD fellowship, 2003-2005</i>
2002-present	Zhong Wu PhD (postdoctoral supervisor)
2003-present	Tonia Foreman PhD (postdoctoral supervisor)
2005-present	Yimin Wu PhD (postdoctoral supervisor)

PEER REVIEWED GRANT STUDY SECTIONS

1998-present	American Cancer Society <i>Study Section: IRG</i> <i>Site: University of Virginia, Charlottesville, VA</i>
1998-2000	U.S. Army Prostate Cancer Research Program <i>Study Section: Cell and Molecular Biology #2</i> <i>1998: Study Section Secretary: Dr. Harold Waters</i> <i>1999: Study Section Secretary: Dr. Dolores Lowry</i> <i>2000: Study Section Secretary: Dr. Dolores Lowry</i>
2004-2009	American Cancer Society <i>Study Section: Cell Structure and Metastasis</i> <i>SRA: Christopher Widnell</i> <i>Site: American Cancer Society, Atlanta, GA</i>

PAST MAJOR PRIOR PEER REVIEWED GRANTS

Principal Investigator: Dan Theodorescu
 Project Number: 9599
 Source: **American Cancer Society**
 Title of Project: Molecular genetics of prostate cancer progression
 Dates of Approved/Proposed Project: 7/1/96-6/30/99

Principal Investigator: Dan Theodorescu
 Project Number: 3476 (grant based in ACS CDA 9599 obtained 7/96)
 Source: **American Cancer Society**
 Title of Project: Molecular genetics of prostate cancer metastasis
 Dates of Approved/Proposed Project: 7/1/00-1/30/03

Principal Investigator: Dan Theodorescu
 Project Number: R29-CA75115 (renewed with R01-CA75115)
 Source: **National Cancer Institute**
 Title of Project: Molecular genetics of bladder cancer progression
 Dates of Approved/Proposed Project: 9/1/97-8/30/02

CURRENT MAJOR PEER REVIEWED GRANTS

Principal Investigator: Dan Theodorescu
 Active/Pending: Active
 Project Number: R01-CA75115 (renewal of grant obtained 9/97)
 Source: **National Cancer Institute**
 Title of Project: Molecular genetics of bladder cancer progression
 Dates of Approved/Proposed Project: 2/1/03-1/30/08

Principal Investigator: Dan Theodorescu
 Active/Pending: Active
 Project Number: R01-CA58123
 Source: **National Cancer Institute**
 Title of Project: Molecular regulation of VEGF in prostate cancer
 Dates of Approved/Proposed Project: 7/1/01-6/30/06

Principal Investigator: Dan Theodorescu
 Active/Pending: Pending
 Project Number: Program Project (patent committee score of 128 from 12/29/04)
 Source: **National Cancer Institute**
 Title of Project: Signal Transduction in Prostate Cancer progression
 Dates of Approved/Proposed Project: 8/1/05-7/30/10

CLINICAL TRIALS

Sponsor: **University of Virginia**
Investigators: Drs. Santen, Myers, Theodorescu, Fisch
Trial: Arimidex, a new second line agent for hormonally refractory prostate cancer
Status: Completed

Sponsor: **Jenssen Pharmaceuticals**
Investigators: 6 teaching institutions in the US.
Trial: The use of a novel oral Farnesyl Transferase Inhibitor in the treatment of BCG refractory bladder cancer.

Status: Completed

Sponsor: **Bard Diagnostic Sciences Inc.**

Investigators: National

Trial: Determining the utility of the BTA assay in establishing cost effective ways to monitor patients with past history of superficial bladder cancer.

Status: Completed

Sponsor: **University of Virginia**

Investigators: Drs. Theodorescu, Thomas

Trial: Ketoconazole-Taxotere for hormone refractory prostate cancer: Phase I with molecular correlates

Status: Application to IRB ongoing

PUBLICATIONS (Indexed)

1. Blair, G.K., Filler, R.M., and Theodorescu, D. 1987. Neonatal pharyngoesophageal perforation mimicking esophageal atresia: clues to diagnosis. *J Pediatr Surg*, 22: 770-774
2. Adams, C., Theodorescu, D., Murphy, E.G., and Shandling, B. 1990. Thymectomy in juvenile myasthenia gravis. *J Child Neurol*, 5: 215-218
3. Theodorescu, D., Cornil, I., Fernandez, B.J., and Kerbel, R.S. 1990. Overexpression of normal and mutated forms of HRAS induces orthotopic bladder invasion in a human transitional cell carcinoma. *Proc Natl Acad Sci U S A*, 87: 9047-9051
4. Cornil, I., Theodorescu, D., Man, S., Herlyn, M., Jambrosic, J., and Kerbel, R.S. 1991. Fibroblast cell interactions with human melanoma cells affect tumor cell growth as a function of tumor progression. *Proc Natl Acad Sci U S A*, 88: 6028-6032
5. Cornil, I., Theodorescu, D., Kerbel, R.S., and Poupon, M.F. 1991. Metastatic dissemination of cancer cells. *Pathol Biol (Paris)*, 39: 300-307
6. Fu, X.Y., Theodorescu, D., Kerbel, R.S., and Hoffman, R.M. 1991. Extensive multi-organ metastasis following orthotopic onplantation of histologically-intact human bladder carcinoma tissue in nude mice. *Int J Cancer*, 49: 938-939
7. Kerbel, R.S., Cornil, I., and Theodorescu, D. 1991. Importance of orthotopic transplantation procedures in assessing the effects of transfected genes on human tumor growth and metastasis. *Cancer Metastasis Rev*, 10: 201-215
8. Theodorescu, D., Caltabiano, M., Greig, R., Rieman, D., and Kerbel, R.S. 1991. Reduction of TGF-beta activity abrogates growth promoting tumor cell-cell interactions in vivo. *J Cell Physiol*, 148: 380-390
9. Theodorescu, D., Cornil, I., Sheehan, C., Man, S., and Kerbel, R.S. 1991. Dominance of metastatically competent cells in primary murine breast neoplasms is necessary for distant metastatic spread. *Int J Cancer*, 47: 118-123
10. Theodorescu, D., Cornil, I., Sheehan, C., Man, M.S., and Kerbel, R.S. 1991. Ha-ras induction of the invasive phenotype results in up-regulation of epidermal growth factor receptors and altered responsiveness to epidermal growth factor in human papillary transitional cell carcinoma cells. *Cancer Res*, 51: 4486-4491

Last Update: Tuesday, February 08, 2005

11. Theodorescu, D., Bergsma, D., Man, M.S., Elshourbagy, N., Sheehan, C., Rieman, D., and Kerbel, R.S. 1991. Cloning and overexpression of TGF-beta 1 cDNA in a mammary adenocarcinoma: in vitro and in vivo effects. *Growth Factors*, 5: 305-316
12. Theodorescu, D., Witchell, S., and Connolly, J. 1991. Chronic adult renal vein thrombosis: two unusual cases and a review of the literature. *Int Urol Nephrol*, 23: 429-435
13. Theodorescu, D., Binnington, A.G., and Connolly, J.G. 1992. The intestinoprostatic capsule anastomosis: functional and anatomic results in a canine model. *Can J Surg*, 35: 169-172
14. Wu*, S.P., Theodorescu, D*, Kerbel, R.S., Willson, J.K., Mulder, K.M., Humphrey, L.E., and Brattain, M.G. 1992. TGF-beta 1 is an autocrine-negative growth regulator of human colon carcinoma FET cells in vivo as revealed by transfection of an antisense expression vector. *J Cell Biol*, 116: 187-196. *(equal first authors)
15. Schuh, A.C., Theodorescu, D., Shalaby, F., and Breitman, M.L. 1993. Altered growth and spontaneous transformation of cells cultured from v-jun transgenic mice recapitulate wound-induced multistage tumorigenesis. *Cell Growth Differ*, 4: 177-184
16. Theodorescu, D., Connors, K.M., Groce, A., Hoffman, R.M., and Kerbel, R.S. 1993. Lack of influence of c-Ha-ras expression on the drug sensitivity of human bladder cancer histocultured in three-dimensions. *Anticancer Res*, 13: 941-946
17. Theodorescu, D., Sheehan, C., and Kerbel, R.S. 1993. TGF-beta gene expression depends on tissue architecture. *In Vitro Cell Dev Biol*, 29A: 105-108
18. Huang, F., Newman, E., Theodorescu, D., Kerbel, R.S., and Friedman, E. 1995. Transforming growth factor beta-1 (tgf-beta-1) is an autocrine positive regulator of colon carcinoma U9 cells in vivo as shown by transfection of a tgf-beta-1 antisense expression plasmid. *Cell Growth Differ*, 6: 1635-1642
19. Theodorescu, D. 1996. Genetic prognostic markers for transitional cell carcinoma of the bladder: From microscopes to molecules. *J. Urol*. 155(1):2
20. Theodorescu, D., Russo, P., Zhang, Z.F., Morash, C., and Fair, W.R. 1996. Outcomes of initial surveillance of invasive squamous cell carcinoma of the penis and negative nodes. *J Urol* 155(5):1626-1631
21. Theodorescu, D. 1996. Prostate Cancer - Our Patients' Questions. *J. Urol*. 155(5):1661-1662
22. Frierson, H. W., Theodorescu, D., and Hannigan, M.C. 1997. Clinicopathological study of gamma-glutamyl transferase (GGT) in benign and malignant prostate. *Mod Pathol* 10(1):1-6.
23. Lajvardi, A., Theodorescu, D., and Older R.O. 1997. A mullerian duct cyst presenting as a complex pelvic mass. *J. Urol*. 157(3):958.
24. Herrel, D., Trachtenberg, J. and Theodorescu, D. 1997. Pelvic lymphadenectomy in prostate cancer: comparison of three surgical techniques. *J. Urol*. 157(4):1337-1339.
25. Theodorescu, D., Broder, S. R., Boyd, J. C., Mills, S. E. and Frierson, H. W. 1997. The use of p53, bcl-2 and Rb protein expression as prognostic markers in localized carcinoma of the prostate. *J. Urol*. 158(1):131-137.
26. Theodorescu, D. 1997. Prognostic factors for relapse in stage I testicular seminoma treated with surveillance - Comment. *J. Urol* 157(5):1709

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28. **Lippert, M. C. and Theodorescu, D.** 1997 The Hautmann neobladder with a chimney: a versatile modification. *J Urol* 158 (4): 1510-1512
29. **Theodorescu, D., Broder, S. R., Boyd, J. C., Mills, S. E., and Frierson, H. F., Jr.** 1997 Chromogranin A as a long-term prognostic markers in localized carcinoma of the prostate. *Cancer* 80 (11): 2109-2119
30. **Theodorescu, D., Lippert, M. C., Broder, S. R., and Boyd, J. C.** 1998 Early PSA failure following radical prostatectomy: The importance of surgical technique. *Urology* 51 (2): 277-282
31. **Theodorescu, D., Balcom, A., Churchill, B.M., and Khoury, A. E.** 1998 Urethral replacement with vascularized tunica vaginalis: defining optimal form of use. *J Urol* 159 (5):1708-1711
32. **Theodorescu, D.** 1998 Correlation between p53 over expression and response to bacillus calmette-guerin therapy in a high risk select population of patients with T1G3 bladder cancer - Comment. *J Urol* 159 (3):791
33. **Theodorescu, D., Laderoute K. R., Calaoagan J. M. and Guldin, K. M.** 1998 Inhibition of human bladder cancer motility by genistein is dependent on epidermal growth factor receptor but not p21ras gene expression. *Int J Cancer* 78(6):775-782
34. **Crane C. H., Clark M., Petroni G., and Theodorescu, D.** 1998 The Bladder Tumor Antigen (BTA) test: performance in patients undergoing pelvic irradiation for non bladder malignancies. *Int J Radiat Oncol Biol Phys* 43(1):73-77
35. **Theodorescu, D., Laderoute, K. R., and Guldin, K. M.** 1998 Epidermal growth factor receptor regulated human bladder cancer motility is a phosphatidylinositol 3-kinase mediated process. *Cell Growth Differ* 9(11):919-928
36. **Theodorescu, D., Frierson, H. W. and Sikes R. A.** 1999 Molecular analysis of surgical margins following radical prostatectomy for localized prostate cancer. *J Urol* 161(5):1442-1448
37. **Gray, M., Petroni G. and Theodorescu, D.** 1999. Urinary function following radical prostatectomy: comparison of retropubic and perineal techniques. *Urology* 53(5):881-890
38. **Harding M. and Theodorescu, D.** 1999 Prognostic markers for adenocarcinoma of the prostate: From microscopes to molecules. *Cancer and Metastasis Reviews* 17(4):429-37
39. **Broder, S. R., Frierson, H. W. and Theodorescu, D.** 1999 Unusual case of non exophytic invasive penile squamous cancer arising from a chronic sinus tract. *Scandinavian Journal of Urology & Nephrology* 33(5):333-35
40. **Lippert, M. C., McClain, R., Boyd, J. C. and Theodorescu, D.** 1999 Alternative Medicine Use in Patients Treated With Curative Intent for Localized Prostate Cancer. *Cancer* 86(12):2642-2648
41. **Gildea, J. J., Golden, W., Harding, M. A., and Theodorescu D.** 2000 The phenotypic and cytogenetic analysis of T24T, a highly tumorigenic subline of the human bladder cancer cell line t24. *Genes Chromosomes and Cancer* 27(3):252-63
42. **Krupsky, T., Frierson, H. W., Petroni G., and Theodorescu, D.** 2000 P53, Rb proteins and area weighted microvessel density are long term survival markers in localized carcinoma of the prostate. *Urology* 55(5):743-9

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44. Sheta, E. A., Harding, M. A., and Theodorescu, D. 2000 Vascular endothelial growth factor is transcriptionally regulated by cell density in prostate cancer cells. *J Natl Cancer Inst* 92(13):1065-73
45. Im, D, Heise, C. E. A., Harding, M. A., O'Dowd, B. F., Theodorescu, D., and Lynch, K. R. 2000 Molecular cloning and characterization of a lysophosphatidic acid receptor, EDG-7, expressed in prostate. *Mol Pharmacol* 57(4):753-9
46. Krupsky, T., Moskaluk, C.A., Boyd, J. C. and Theodorescu, D. 2000 Classical markers and area weighted microvessel density in the prediction of clinical stage of carcinoma of the bladder. *Br J Urol* 85(9):1027-32
47. Gildea, J. J., Harding, M. A., and Theodorescu D. 2000 A novel and quantitative assay to measure genetic and pharmacologic effects on tumor cell motility and invasion. *BioTechniques* 29:81-86
48. Gardner, T. A., Bissonette, E., Petroni, G., Sokoloff, M., McClain, R., and Theodorescu, D., 2000 Operative and postoperative factors affecting length of stay following radical prostatectomy. *Cancer* 89: 424-430
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51. Coblentz, T., Mills, S. E. and Theodorescu, D., 2001. The value of second opinion pathology in the evaluation of patients referred for radical cystectomy. *Cancer*. 91(7):1284-90
52. Fulmer, B., Petroni G, and Theodorescu, D. 2001. Prospective comparison of sexual and voiding function in patients treated by either radical prostatectomy or brachytherapy for clinically localized prostate cancer. *Cancer*. 91(11):2046-55
53. Krupsky, T., Harding, M. A., and Theodorescu, D. 2001. The role of vascular endothelial growth factor in the tissue specific in vivo growth of prostate cancer cells. *Growth Factors* 18: 287-302
54. Seraj, M. J., Gildea, J. J., Harding, M. A., and Theodorescu, D. 2001. Molecular determination of perivesical and lymph node metastasis following radical cystectomy for urothelial carcinoma of the bladder. *Clinical Cancer research* 7: 1516-1522
55. Seraj, M. J., Gildea, J. J., Harding, M. A., and Theodorescu, D. 2001. Metastatic potential and metastasis related gene expression of lineage related human bladder cancer cell lines. *Clinical and Experimental Metastasis* 18: 519-525
56. Fulmer, B., Petroni G, and Theodorescu, D. 2001. PSA velocity at tumor recurrence following radical prostatectomy: a surrogate marker for increased tumor aggressiveness in African American men. *J Urol* 166:1328-1331
57. Smith, E. and Theodorescu, D. 2001. Evaluation of urinary continence and voiding function: Early results in men with the neourethral modification of the Hautmann orthotopic neobladder. *J Urol* 166: 1346-1349
58. Santen, R. J., Fisch, M., Myers, C., Theodorescu, D., Petroni, G., and Cohen, R. 2001. Use of the Aromatase Inhibitor Anastrozole in the Treatment of Advanced Prostate Cancer. *Cancer* 92: 2095-2101

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60. Chen, C., Frierson, H. F., Haggerty, P. F., Theodoreescu, D., Gregory, C. W., Dong, J.T. 2001. An 800 kb Region of Deletion at 13q14 in Human Prostate and Other Carcinomas. *Genomics* 77: 135-144
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74. Miller, N. Bissonette, E., and Theodoreescu, D. 2003. The impact of a novel neoadjuvant hormonal therapy on the quality of life of patients treated by brachytherapy for clinically localized prostate cancer? *Cancer* 97: 1203-1210

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79. Hall, J., Bissonette, E., Theodorescu, D. 2003. Motivations for use of complementary medicine in patients with localized prostate cancer treated with curative intent. *British J. Urol* 91: 603-607
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87. Bassignani MJ, Moore Y, Watson L. and Theodorescu, D. 2004. Pilot Experience with Real-Time Ultrasound Guided Percutaneous Renal Mass Cryoablation *J. Urol* 171(4):1620-3
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